

## REMARKS

Applicant thanks the Examiner for entering the RCE filing and for entering and considering Applicant's submission of 12 March, 2010.

Applicant thanks the Examiner for withdrawal of a number of previous rejections in light of Applicant's previous submission.

Independent claims 23 and 33 have been amended to remove recitation of "an amylin" and recite the amylin agonist as an amylin agonist analogue of the formula provided in each claim. Claim 23 incorporates the formula of claim 68 and claim 33 incorporates the formula of claim 72. Consistent with this recitation, claims 24, 34, 68 and 72 are canceled. Claims 80, 82 and 84 were amended to remove the term "about". Accordingly, the independent claims are claims 23, 33 and 76, which all recite a specific formula of amylin agonist analogues. Remaining claims have been amended to adjust claim dependencies.

In view of the amendments, pending (including withdrawn but not canceled claims) are Claims 23, 25, 27-29, 31-33, 35, 37-39, 69-71, 73-80, 82, 84-90, and 95-97.

Claims 80, 82 and 84 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, Claims 80, 82 and 84 were viewed as vague and indefinite in the limitation "about" because it was alleged as unclear what precise amount or range of amounts is encompassed within the scope of this limitation, and that one of ordinary skill in the art would not be reasonably apprised of the scope of the claim. Applicant submits that "about" would be viewed in the context of its use, such that one of skill in the art would understand the generally accepted deviations due to manufacturing processes and/or delivery devices. Without acquiescing to the reasons for rejection, Applicant has amended claims 80, 82 and 84 to remove the term "about." Withdrawal of the rejection is requested.

The present claim amendments, which remove the term “amylin” and recites a formula for the amylin agonist analogue that does not include amylin or pramlintide, moot the various rejections of claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and/or 82 as anticipated under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 102(e)(2) and/or rejected under obviousness type double patenting. Withdrawal of these rejections is requested. To be clear, the Applicant is not acquiescing to the various rejections, but is presenting the current amendments solely to expedite an allowance.

Claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 were alleged as unpatentable under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope of the claims for the reasons set forth in paragraph 24 of the Office Action mailed 2/11/08 and maintained in paragraph 13 of the Advisory Action mailed 08/28/08 and paragraphs 9(A) and 10(1) of the Examiner’s Answer mailed 02/13/09.

Applicant notes that the claims have been amended to specifically define the amylin agonist as an amylin agonist peptide of the specific formula now recited in each of the 3 independent claims.

The Examiner’s Answer (see e.g., at the paragraph bridging pages 3 and 4) appears to state that the only claim that would be enabled would be a claim that exactly duplicates all the conditions in the patent application’s Examples. Applicant’s specification when viewed as a whole, including Examples 1-3, provides guidance for the skilled artisan to practice the claimed invention without undue experimentation for the reasons already of record. See for example Applicant’s Brief on Appeal filed 29 October 2008, the contents of which are incorporated herein by reference. With the guidance provided, including that exemplified in the Examples, undue experimentation would not be required to practice the invention as now claimed.

Furthermore, the key basis for the rejection appears to rely on comments made in an Appeal Brief in the parent application in response to a rejection based on US Patent 5,739,106 to Rink et al. Specifically, the Examiner’s Answer at pages 9 to 10 presented and discussed the Applicant’s comments as evidence of non-enablement of the present claims directed to treating obese patients, and further as evidence to doubt the objective truth of the teachings of the present

application to compounds other than pramlintide. The Applicant had noted that Rink *et al.* reported that rat amylin administered under specific conditions did not lead to a reduction in food intake, and presumably would not have been expected to lead to a reduction in body weight. However, the conditions of Rink *et al.* were that rat amylin was administered alone to young, lean mice intraperitoneally once at 1 ug/kg dose, for which a reduction in food intake was not observed as determined by a measurement taken only 30 minutes post the IP injection. This specific experimental protocol and result, not even directed to obese subjects, and examining an acute effect, does not lessen the veracity of the teachings of the present application directed to treating obese patients as claimed using amylin agonist analogues.

Further to this point, submitted herewith is a post-filing publication (Mack *et al.* 2003; **Exhibit 1**) teaching that rat amylin administered chronically does lead to body weight loss in obese subjects, supporting the credibility of the specification's teaching regarding compounds other than pramlintide that was used in the specification's Examples. See Mack *et al.*, "Sustained reduction in food intake and body weight in high fat-fed rats during 28-day amylin infusion," *Diabetes* 2003 Jun; 52(suppl 1):A389. Abstract 1690-P."

Accordingly, it is credible that the present claims as amended are enabled by the specification. Withdrawal of this rejection is respectfully requested.

### **Conclusion**

Applicant believes that all issues raised in the Office Action have been properly addressed in this response. Accordingly, Applicant respectfully requests entry of the amendments to the claims presented herein, and allowance of the instant Claims. If there are any issues remaining, or if the Examiner has any questions, the Examiner is invited to call the undersigned directly at 858-754-7544 so that the issues can be addressed promptly.

No additional fees associated with this submission, or otherwise associated the instant case, are believed due. However, if such a fee is due, the Commissioner is hereby authorized to charge payment of any such fees to Applicant's Deposit Account No. 010535 referencing Docket

No. 235/013US. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Respectfully submitted,  
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